

REMARKS

A final Office Action was mailed May 15, 2007 (the "Office Action") in connection with the present application. On November 14, 2007, Applicants' representatives filed in the United States Patent and Trademark Office ("USPTO") a Notice of Appeal from the Examiner to the Board of Patent Appeals and Interferences and a Petition for Extension of Time for three (3) months. The present Amendment, which is responsive to the Office Action, is being filed in the USPTO with a Request for Continued Examination Under 37 C.F.R. § 1.114, a Petition for Extension of Time for three (3) months, a Supplemental Information Disclosure Statement and revised form PTO-1449 "List of References Cited by Applicant" form with copies of references C35-C40. Entry of the following amendments to the claims and specification and consideration of these remarks is respectfully requested.

I. Amendments to the Claims

Claims 52-78 were pending in this application. Applicants have canceled claims 52-78, without prejudice to Applicants' right to pursue the subject matter of the canceled claims in one or more related applications. Applicants have added new claims 79-96 to more particularly point out and distinctly claim that which Applicants regard as their invention. The new claims are fully supported by the specification and claims as originally filed. Support for the new claims may be found in the specification, *inter alia*, as summarized in the Claim Support Chart below. Thus, the new claims do not constitute new matter. Upon entry of this amendment, claims 79-96 will be pending in this application.

Claim Support Chart

Claim	Support in specification as filed (U.S. application Serial No. 10/713,732)
79	p. 6, ll. 6-14 and ll. 27-35; p. 7, ll. 3-10; p. 8, ll. 4-15; p. 11, ll. 6-22; p. 12, ll. 28-39; p. 13, ll. 29-36; p. 17, l. 36 to p. 18, l. 12; p. 18, ll. 22-26; p. 30, ll. 20-26; p. 31, ll. 33-36; Example of Section 6 starting at p. 37; Example of Section 8 starting at p. 43; claim 49 as filed
80	See support for claim 79
81	p. 8, l. 37 to p. 9, l. 1; p. 19, ll. 24-36; p. 20, ll. 9-29
82	p. 8, l. 37 to p. 9, l. 1; p. 19, ll. 24-36; p. 20, ll. 30-36

Claim Support Chart (continued)

Claim	Support in specification as filed (U.S. application Serial No. 10/713,732)
83	p. 17, ll. 38-39 and p. 18, ll. 22-26; particularly Example of Section 6 starting at p. 37
84	p. 17, ll. 38-39 and p. 18, ll. 22-26; Example of Section 7 starting at p. 41
85	Example of Section 6 starting at p. 37
86	p. 32, ll. 1-2 and ll. 20-30; p. 36, l. 37 to p. 37, l. 4
87	p. 13, ll. 17-19; p. 32, ll. 26-30
88-96	p. 32, ll. 3-7; p. 34, ll. 26-40

**The Rejections Under 35 U.S.C. § 112,
First Paragraph, Lack of Enablement, Should Be Withdrawn**

Claims 52, 54, 56-68, and 70-78 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for the full breadth of the claimed subject matter. Claims 53, 55 and 69 are objected to for being dependent on a rejected base claim. The rejection and objection are obviated and/or overcome by the present claim amendments.

While admitting that the specification is enabling for a method for inducing an immune response against an influenza virus having a truncated NS1 protein of 99 amino acids, the Examiner alleges that the specification fails to enable a method for inducing an immune response to a subunit vaccine for HIV, hepatitis B, herpes, polio, and bacterial or parasitic related diseases or the prevention of diseases related to influenza, HIV, herpes, polio, bacteria or parasites. In order to expedite prosecution and without conceding to the propriety of the rejection, Applicants have deleted claims 52, 54, 56-68, and 70-78 and added new claims that specify an influenza virus with a genome encoding a truncated NS1 protein composed of amino acid residues 1 to 99 of the NS1 protein of the same or a different influenza virus strain. Influenza A strain NS1/99, which the Examiner acknowledges is enabled for protecting against challenge with wild-type influenza (Office Action at p. 3 and 4), is an example of such a virus.

Therefore, Applicants believe that the present amendment addresses and obviates the Examiner's rejection of claims 52, 54, 56-68, and 70-78 under 35 U.S.C. § 112, first paragraph, for lack of enablement.

II. Amendments to the Specification

Applicants have amended the first paragraph of the specification to update the continuity data to reflect that priority document U.S. application Serial No. 09/332,288 issued as U.S. Patent No. 6,669,943 on December 30, 2003.

Applicants have also amended the paragraph bridging pages 18 and 19 of the specification to incorporate the following sentences from the priority application, U.S. Application Serial No. 60/117,683 (the "'683 application"), which is incorporated into the instant specification by reference in its entirety (see specification at page 1, lines 9-13):

The present invention encompasses genetically engineering any influenza A or B virus such that the genome of the engineered virus comprises a mutation in the NS1 gene corresponding to the NS1 mutation found in naturally ~~occurring~~ occurring mutants NS1/80, NS1/124, A/Turkey/ORE/71, B/201 or ~~AWB4-234~~ AWBY-234, with the proviso that the present invention does not comprise the following influenza mutants: A/Turkey/Ore/71, B/201 and ~~AWB4-234~~ AWBY-234 as they occur in nature.

This sentences may be found in the '683 application at page 13, lines 7-15. Applicants have corrected the typographical errors in the sentence being incorporated by reference from the '683 application with corrections indicated by underlining/strikethrough above. One of skill in the art reading the '683 application would have understood that these are obvious errors. For example, the correct term "AWBY-234" is introduced in the same paragraph (see the '683 application at page 13, lines 5-7).

Applicants have further amended the paragraph bridging pages 18 and 19 to correct obvious errors in the number of amino acid residues derived from NS1 in the

influenza B virus strains B/201 and B/AWBY-234. The specification, citing Norton *et al.* (reference CH of record in the subject application; "Norton"), discloses that strain B/201 has an NS1 truncation comprising 127 amino acids derived from the N-terminus. However, Norton discloses that strain B-201 has an NS1 truncation of 110 amino acids derived from the NS1 N-terminus. The C-terminal 17 amino acids are encoded by a different reading frame. (See Norton, p. 207, right column, 2nd full paragraph and Figure 2 at pages 208-9.) The specification, citing Tobita *et al.* (reference CW of record in the subject application; "Tobita"), discloses that strain B/AWBY-234 is a virus having an NS1 truncation such that it comprises 90 amino acids derived from the N-terminus. However, Tobita teaches that strain B/AWBY-234 has an NS1 truncation of 89 amino acids derived from the NS1 N-terminus. Amino acid residue 90 is the result of a frameshift mutation, and is not an amino acid derived from NS1 N-terminus. (See Tobita, in particular Figure 2 at page 316). One of skill in the art as of the filing date of the instant application would have understood, reading Norton and Tobita, that these are obvious errors. Applicants have also amended the specification at page 37 to correct a typographical error. The amendments to the specification do not introduce new matter.

CONCLUSION

Applicants believe that the present claims meet all the requirements for patentability. Entry of the foregoing amendments and remarks into the file of the application is respectfully requested. Withdrawal of all rejections and consideration of the amended claims are requested.

If any issues remain, the Examiner is urged to telephone the undersigned.

Respectfully submitted,

Date: April 11, 2008


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Enclosures